Complete Summary

GUIDELINE TITLE

Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis.

BIBLIOGRAPHIC SOURCE(S)

American Society of Nephrology, Renal Physicians Association. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. Washington (DC): Renal Physicians Association; 2000 Jan. 124 p. [302 references]

Galla JH. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. Renal Physicians Association and the American Society of Nephrology. J Am Soc Nephrol 2000 Jul;11(7):1340-2. [302 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Acute renal failure (ARF)
- End-stage renal disease (ESRD)

GUIDELINE CATEGORY

Risk Assessment
Treatment

CLINICAL SPECIALTY

Internal Medicine
Nephrology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physician Assistants
Physicians
Social Workers

GUIDELINE OBJECTIVE(S)

- To synthesize available research evidence on patients with acute renal failure (ARF) and end-stage renal disease (ESRD) as a basis for making recommendations about withholding and withdrawing dialysis;
- To enhance understanding of the principles and processes useful for and involved in making decisions to withhold or withdraw dialysis;
- To promote ethically as well as medically sound decision-making in individual cases;
- To recommend tools that can be used to promote shared decision-making in the care of patients with ARF or ESRD; and
- To offer a publicly understandable and acceptable ethical framework for shared decision-making among health care providers, patients, and their families.

TARGET POPULATION

- Adult patients with either acute renal failure or end-stage renal disease.
- Pediatric patients are not directly addressed; however, many of the principles discussed in the guideline may apply.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Shared decision-making in the appropriate initiation of and withdrawal from dialysis
2. Informed consent or refusal
3. Estimating prognosis
4. Conflict resolution
5. Advance directives
6. Withholding or withdrawing dialysis
7. Time-limited trial of dialysis
8. Palliative care

MAJOR OUTCOMES CONSIDERED

For acute renal failure:

- Survival
- Recovery of renal function
- Progression to end-stage renal disease

For end-stage renal disease:

- Survival
- Quality of life
- Functional status
- Complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategy for Relevant Research Evidence

Pertinent English language literature published from 1985 to December 1998 was identified from the following:

- Electronic databases (MEDLINE, CINAHL, HealthStar, PsycINFO, and EMBASE)
- References from articles
- Experts
- Hand searches of eight medical and nephrology journals of issues covering the last six months of 1998

Research evidence based on data collected before 1985 was not sought because marked technological advances in dialysis delivery have occurred since that time. Preliminary searches of electronic databases using specific search terms, such as dialysis, acute renal failure or end-stage renal disease and withdrawal, preferences, prognosis, or quality of life, did not adequately capture the array of literature of interest to the Working Group. Thus a very broad search strategy was used; it only included terms for dialysis, end-stage renal disease, and acute renal failure, and it excluded unpublished studies, case reports, editorials, and letters.

Selection of Relevant Research Evidence

Several types of information were deemed relevant to the key questions (see Selection Criteria, Table 2 in the original guideline document). For information about prognosis in patients with end-stage renal disease (ESRD), large retrospective or prospective cohort studies with at least 100 patients that examined multivariate predictors of mortality or morbidity were selected. For information about prognosis in patients with acute renal failure (ARF), smaller retrospective or prospective studies involving at least 20 dialysis patients and reporting mortality outcomes were used. Information relevant to who gets

referred for dialysis and when, feasibility, withdrawal frequencies and reasons, patient preferences, shared decision-making, advance directives, and quality of life assessments was taken from descriptive surveys, case-control studies, cohort studies, or randomized trials with at least 20 patients who were receiving or awaiting dialysis. Research evidence from Asian and developing countries was not used because differences in access to dialysis, patients' values and preferences, and decision-making processes were considered likely to limit generalizability and applicability to patients in the United States.

Abstracts of the 5,283 potentially eligible records were screened by at least two persons to identify those meeting selection criteria. Of these, 4,718 were excluded, usually because they addressed short-term complications, physiologic parameters, management or adequacy of dialysis, or because they did not contain primary data. The full texts of the remaining 565 articles were retrieved and reviewed by at least two persons to ascertain final eligibility. Of 329 articles meeting criteria, 29 contained information from the same study populations leaving 300 unique studies for review. A physician with clinical and methodological expertise resolved disagreements about eligibility criteria.

NUMBER OF SOURCE DOCUMENTS

- 5,283 records were examined
- Of these, 565 articles were retrieved.
- Of these, 300 unique articles met the Selection Criteria (see Selection Criteria, Table 2 in the original guideline document).

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Different Types of Studies:

Criteria for rating studies addressing therapy, prevention, and prognosis were adapted from the Centre for Evidence-based Medicine at Oxford's criteria for rating evidence. Criteria for rating observational evidence were developed by the San Antonio Evidence-based Practice Center.

Observational/Descriptive Evidence:

A. Multiple large studies or single nationally representative study with >80 percent response rate(s).
B. Multiple small studies from diverse populations with response rates of 60%-80%.
C. Few studies, selective samples, or low response rates.

Therapy/Prevention

A. Multiple randomized controlled trials or single trial with narrow confidence interval.
B. Cohort study or low quality randomized trial (e.g., < 80% follow-up, small sample size, unequal co-interventions or biased outcome assessment).
C. Case-control studies.

Prognosis

A. Inception cohort studies (multiple or single large representative study) with > 80% follow-up, and/or models from such studies validated with test sets.
B. Retrospective cohort study, prevalent cohort study, or follow-up of untreated control patients in a randomized trial, or multiple studies find similar risk ratios for a given risk factor.
C. Case-control studies or biased cohort studies with inadequate control for confounding variables, biased outcome, or biased exposure ascertainment.

METHODS USED TO ANALYZE THE EVIDENCE

Decision Analysis
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Two analytic frameworks, one for acute renal failure (ARF) and one for end-stage renal disease (ESRD), were developed to provide a conceptual framework for decisions about withholding or withdrawing dialysis. The models are presented in Figures 3 and 4 in the original guideline document. They depict a dynamic chronological sequence of decision-making that is informed by multiple factors, such as patient preferences, prognosis, and feasibility of dialysis.

The Working Group proposed and prioritized key questions related to the models using a combined nominal and modified Delphi process. Questions specified information that was either desirable or necessary to make informed and ethical decisions about withholding or withdrawing dialysis. Such questions were categorized as directly informative to the evidence model or as background and contextual in nature.

These key questions guided analysis of the evidence. The specific evidence questions for decision-making about dialysis in ARF and ESRD are listed in the original guideline document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Working Group formulated specific guideline recommendations taking into account ethical principles, legal statutes, shared decision-making, the amount,

type, quality, and consistency of supporting research evidence, and the anticipated feasibility of implementation.

The Working Group was provided with background information regarding principles of ethical decision-making. They were also given information regarding guideline development processes and desirable attributes of performance measures that may be used to help insure guideline implementation. They were provided with evidence tables that summarized the available research evidence relevant to the analytic framework questions. Based on these materials, teams within the Working Group formulated draft guideline recommendations. A general consensus process involving the entire group was used to reach agreement on final recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline identifies twenty-seven individuals who served as peer reviewers.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation No. 1: Shared Decision-Making

A patient-physician relationship that promotes shared decision-making is recommended for all patients with either acute renal failure (ARF) or end-stage renal disease (ESRD). Shared decision-making should involve at a minimum the patient and the physician. If a patient lacks decision-making capacity, decisions should involve the patient´s legal agent. With the patient's consent, shared decision-making may include family members or friends and other members of the renal care team.

Recommendation No. 2: Informed Consent or Refusal

Physicians should fully explain diagnosis, prognosis, and all treatment options to each patient. The explanation of treatment options should include: (1) available dialysis modalities, (2) not starting dialysis and continuing conservative management which should include end-of-life care, (3) a time-limited trial of

dialysis, and (4) stopping dialysis and receiving end-of-life care. Choices among options should be made by patients or, if patients lack decision-making capacity, their designated legal agents. Their decisions should be informed and voluntary. The renal care team, in conjunction with the primary care physician, should insure that the patient or legal agent understands the consequences of the decision.

Recommendation No. 3: Estimating Prognosis

To facilitate informed decisions about starting dialysis for either ARF or ESRD, discussions should occur with the patient or legal agent about life expectancy and quality of life. Depending upon the circumstances (e.g., availability of nephrologists), a primary care physician or nephrologist who is familiar with prognostic data should conduct these discussions. These discussions should be documented and dated. Chances for survival should be estimated for all patients requiring dialysis, with the realization that the ability to predict survival in the individual patient is difficult and imprecise. The estimates should be discussed with the patient or legal agent, the patient's family, and among the medical team. For patients with ESRD, these discussions should occur as early as possible in the course of the patient's renal disease and continue as the renal disease progresses. For patients who encounter major complications that may substantially reduce survival or quality of life, it is appropriate to discuss and/or reassess treatment goals, and to consider withdrawing dialysis.

Recommendation No. 4: Conflict Resolution

A systematic approach for conflict resolution is recommended when disagreement exists regarding the benefits of dialysis between the patient or legal agent (and those supporting the patient's position) and a member(s) of the renal care team. Conflicts may also occur within the renal care team or between the renal care team and other health care providers. This approach should review the shared decision-making process for the following potential sources of conflict: (1) miscommunication or misunderstanding about prognosis, (2) intrapersonal or interpersonal issues, and/or (3) values. If dialysis is indicated emergently, it should be provided while pursuing conflict resolution, provided the patient or legal agent requests dialysis.

Recommendation No. 5: Advance Directives

The renal care team should attempt to obtain written advance directives from all dialysis patients. These advance directives should be honored.

Recommendation No. 6: Withholding or Withdrawing Dialysis

It is appropriate to withhold or withdraw dialysis for patients with either ARF or ESRD for:

- Patients with decision-making capacity who, being fully informed and making voluntary choices, refuse dialysis or request dialysis be discontinued.
- Patients who no longer possess decision-making capacity who have previously indicated refusal of dialysis in an oral or written advance directive.

- Patients who no longer possess decision-making capacity and whose properly appointed legal agents refuse dialysis or request that it be discontinued.
- Patients with irreversible, profound neurological impairment such that they lack signs of thought, sensation, purposeful behavior, and awareness of self and environment.

Recommendation No. 7: Special Patient Groups

It is reasonable to consider not initiating or withdrawing dialysis for patients with ARF or ESRD who have a terminal illness from a nonrenal cause or whose medical condition precludes the technical process of dialysis.

Recommendation No. 8: Time-Limited Trials

For patients requiring dialysis, but who have an uncertain prognosis or for whom a consensus cannot be reached about providing dialysis, nephrologists should consider offering a time-limited trial of dialysis.

Recommendation No. 9: Palliative Care

All patients who decide to forego dialysis (or for whom such a decision is made) should receive continued palliative care. With the patient's consent, persons with expertise in such care, such as hospice health care professionals, should be involved in managing the medical, psychosocial, and spiritual aspects of end-of-life care for these patients. Patients should be allowed to decide if they wish to die in a health care facility or at home with hospice care. Bereavement support should be offered to patients' families.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

There was considerable heterogeneity among the types of questions that the Working Group posed and in the types of research studies that were deemed relevant to those questions. Most often, relevant studies were prognostic cohort studies or observational studies (e.g., surveys, case series) that provided descriptive information. In a few instances, randomized controlled trial evidence was considered relevant.

In most instances, research evidence was contextual in nature and only provided indirect support to the recommendations. The text in the rationales for each recommendation in the guideline document gives the ranking for the body of research evidence relevant to individual statements. When multiple relevant studies of varying quality were available, the evidence was rated according to the highest ranked study. Meta-analysis was not used to quantitatively summarize study data because of the marked heterogeneity in study designs and study

populations, and because quantitative techniques for summarizing prognostic studies that use multivariate analysis are not well developed.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This Guideline addresses withholding and withdrawing dialysis in adult patients with either acute renal failure (ARF) or end-stage renal disease (ESRD). Shared decision-making (the process by which physicians and patients agree on a specific course of action based on a common understanding of the treatment goals and risks and benefits of the chosen course compared with reasonable alternatives) is recommended. Shared decision-making recognizes the importance of both patient preferences and medical indications. In shared decision-making, the health care provider is the expert in diagnosis, prognosis, and treatment alternatives, and the patient is the expert in his or her own history, values, preferences, and goals. The two work together to reach decisions that are individualized to the patient's particular circumstances and preferences.

There are limits, however, to the shared decision-making process that protect the rights of patients and the professional integrity of health care professionals. The patient has the right to refuse dialysis even if the renal care team disagrees with the patient's decision. Similarly, the renal care team has the right to refuse to offer dialysis when the expected benefits do not justify the risks. Recognizing that there are circumstances in which patients and renal care teams disagree about decisions to start, continue, or stop dialysis, this Guideline provides recommendations for how to resolve such conflicts.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations are not mandatory, but rather flexible guides that can be tailored to a particular patient, provider, and geographic circumstances. They allow the renal care team to use discretion as they are applied to individual patients. They are intended for use by providers and patients (and their families or advisors) in the United States of America and its trust territories to aid in dialysis decision-making. They are not intended for use by regulatory agencies for reimbursement or other decisions.

Decisions to either withhold or withdraw dialysis are complex and dependent upon circumstances unique to individual patients and their providers. Although these recommendations are meant to aid in dialysis decision-making, they do not cover every possible contingency. Further, the guideline recommendations do not cover the technical management of patients receiving dialysis nor the selection of patients for renal transplantation, topics which were recently addressed by the

Renal Physicians Association (RPA), the National Kidney Foundation, and the American Society of Transplantation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Dissemination and Educational Initiatives

A first step in Guideline implementation is dissemination and education. The Working Group recommended that the Guideline document be disseminated throughout the End-Stage Renal Disease (ESRD) Networks, as well as to individual providers. They also recommended incorporation of the Guideline into training programs and continuing education workshops for practicing renal care professionals. ESRD Networks, professional organizations, and/or providers may use the Guideline to develop patient education materials. Training programs and workshops should provide opportunities for participants to develop and practice skills necessary for implementing the Guideline, such as skills in communication and providing palliative care.

Local Implementation

Clinical practice guidelines are successful only to the extent that they improve patient care and outcomes. The limited data available suggest substantial variation among dialysis facilities with regard to advance care planning, completion of advance directives, and provider/patient (family or legal agent) communication regarding treatment options (including the right to refuse dialysis). One of the fundamental principles of Continuous Quality Improvement (CQI) is that opportunities for improvement exist whenever there is variability in process and outcomes. Dialysis facilities and their patients could benefit from CQI activities that seek to increase communication and shared decision-making between providers and patients or their legal agents regarding treatment and end-of-life decisions.

Quality improvement consists of a cycle of identifying areas in need of improvement, setting achievable goals, targeting activities to achieve these goals, and remeasuring performance. Choosing reliable, specific, valid, reproducible, and interpretable quality indicators will help insure successful implementation and desired improvements in care.

With these factors in mind, potential quality indicators derived from this Guideline are suggested below to assist local facilities in their CQI efforts. Depending upon current local practices and available resources, individual facilities are encouraged to consider selecting one or more of the following areas for CQI activities.

- Assessment and documentation of decision-making capacity for patients entering the unit and at annual evaluations. Assessment of decision-making capacity should include a formal mental status exam and depression screening. Patients who were previously functioning within normal range and who are found to have significant deterioration/impairment may be referred for further evaluation and possible treatment.

- For those patients who lack decision-making capacity, documentation of legal agent name and contact information.
- Annual advance care planning as part of treatment planning that documents (easily accessible on facility chart) advance directives (e.g., living wills, durable power of attorney for health care) or refusal to complete same after staff/physician education and counseling.
- Reassessment of decision-making capacity and care plan review triggered by specific intercurrent events that are known to dramatically increase mortality (e.g., myocardial infarction [MI], stroke, foot amputation) or by a deterioration in functional status as evidenced by a loss of independence in daily living.
- Staff/physician training in counseling techniques for advance care planning and shared decision-making.
- Specific staff member(s) designated as responsible for providing education and counseling for advance care planning and/or documenting that it is taking place.
- Provision and documentation of continued palliative care for patients who decide to discontinue dialysis and documentation of satisfaction of patient and family with palliative care.
- Evaluation and documentation of decisions to perform time-limited trials of dialysis for patients with uncertain prognoses or for whom consensus regarding dialysis could not be reached, and documentation of formal reassessment at the end of the time-limited trial date.
- Establishment, use, and documentation of outcomes of mediation and ethics consultation services provided by local ethics committees and the ESRD Networks.

Suggestions and examples of some tools (e.g., methods for assessing decision-making capacity) that might be used to implement these recommendations are provided in the Toolkit in the original guideline document.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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withdrawal from dialysis. Washington (DC): Renal Physicians Association; 2000 Jan. 124 p. [302 references]

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jan

GUIDELINE DEVELOPER(S)

American Society of Nephrology - Professional Association
Renal Physicians Association - Medical Specialty Society

SOURCE(S) OF FUNDING

Renal Physicians Association (RPA)
American Society of Nephrology (ASN)

GUIDELINE COMMITTEE

Renal Physicians Association-American Society of Nephrology (RPA-ASN) Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The Working group was comprised of representatives from the following organizations, in addition to a health policy analyst with expertise in the Medicare End-Stage Renal Disease (ESRD) program and a bioethicist with extensive knowledge of dialysis issues:

- American Academy of Family Practice
- American Association of Kidney Patients
- American College of Physicians-American Society of Internal Medicine
- American Nephrology Nurses Association
- American Society of Nephrology
- American Society of Pediatric Nephrology
- American Society of Transplantation
- Council of Nephrology Social Workers
- Health Care Financing Administration
- National Kidney Foundation
- National Renal Administrators Association
- Renal Physicians Association
- The Forum of ESRD Networks

Working Group Members: Alvin H. Moss, MD; William F. Owen, Jr., MD; Richard Albert, MD; Eileen Brewer, MD; Helen Danko, MS, RN; John H. Galla, MD; Roman M. Hendrickson, MD; Albert R. Jonsen, PhD; Judith Kari, MSW; Bertram Kasiske, MD; Karren King, MSW; Jenny Kitsen; John M. Newmann, PhD, MPH; Christy A. Price, RN, MSN; Richard Rettig, PhD; Dale Singer, MHA.

In addition, other individuals including the staff from the San Antonio Evidence-Based Practice Center and VA Cochrane Center were acknowledged in the guideline document for their contribution to the project.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Association of Kidney Patients, Inc. - Disease Specific Society
American Nephrology Nurses' Association - Professional Association
American Society of Pediatric Nephrology - Professional Association
Forum of End-Stage Renal Disease Networks - Private Nonprofit Organization
National Kidney Foundation - Disease Specific Society
National Renal Administrators Association - Professional Association

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: An executive summary is available from the Renal Physicians Association (RPA) Web site.

Print copies: Available from the Renal Physicians Association, 4701 Randolph Rd, Suite 102, Rockville, MD 20852; e-mail, rpa@renalmd.org; telephone, (301) 468-3515; fax, (301) 468-3511.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 8, 2000. The information was verified by the guideline developer on March 10, 2000.

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